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NBDL-89R003

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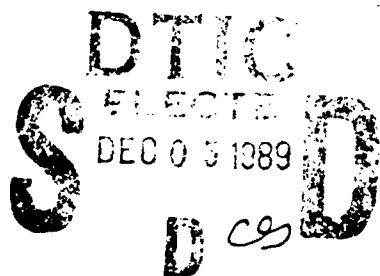
GUIDELINES FOR SAFE HUMAN EXPOSURE TO IMPACT ACCELERATION

UPDATE A

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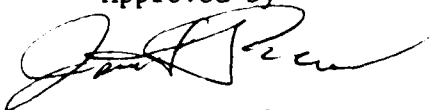
Prepared for

Naval Military Research and Development Command
Bethesda, MD 20014

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Volunteer subjects were recruited, evaluated, and employed in accordance with the procedures specified in Department of Defense Directive 3216.2. Secretary of the Navy Instruction 3900.39 series and Bureau of Medicine and Surgery Instruction 3900.6 series. These instructions meet or exceed the provisions of prevailing national and international guidelines.

The animals used in this work were handled in accordance with the principles outlined in the "Guide for the Care and Use of Laboratory Animals (National Institutes of Health Document No. NIH 80-23)," established by the Institute of Laboratory Animal Resources, National Research Council.

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REPORT DOCUMENTATION PAGE

1a REPORT SECURITY CLASSIFICATION Unclassified			1b RESTRICTIVE MARKINGS N. A.		
2a SECURITY CLASSIFICATION AUTHORITY N. A.			3 DISTRIBUTION AVAILABILITY OF REPORT Approved for public release; distribution unlimited.		
2b DECLASSIFICATION/DOWNGRADING SCHEDULE N. A.					
4 PERFORMING ORGANIZATION REPORT NUMBER(S) NBDL-89R003			5 MONITORING ORGANIZATION REPORT NUMBER(S)		
6a NAME OF PERFORMING ORGANIZATION Naval Biodynamics Laboratory		6b OFFICE SYMBOL (If applicable)		7a NAME OF MONITORING ORGANIZATION	
6c ADDRESS (City, State, and ZIP Code) P. O. Box 29407 New Orleans, LA 70189-0407			7b ADDRESS (City, State, and ZIP Code)		
8a NAME OF FUNDING SPONSORING ORGANIZATION Naval Medical Research and Development Command		8b OFFICE SYMBOL (If applicable)		9 PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER	
8c ADDRESS (City, State, and ZIP Code) Bureau of Medicine and Surgery National Capitol Region Bethesda, MD 20814-3850			10 SOURCE OF FUNDING NUMBERS		
			PROGRAM ELEMENT NO 63216N	PROJECT NO M0097	TASK NO .001
			WORK UNIT ACCESSION NO		
11 TITLE (Include Security Classification) Guidelines for Safe Human Exposure to Impact Acceleration, Update A (U)					
12 PERSONAL AUTHOR(S) Weiss, Marc S., Ph.D. Matson, David L., Ph.D. Mawn, Stephen V., LCDR, MC, USNR					
13a TYPE OF REPORT Scientific		13b TIME COVERED FROM N. A. TO		14 DATE OF REPORT (Year, Month, Day) 890901	
				15 PAGE COUNT 15	
16 SUPPLEMENTARY NOTATION					
17 COSATI CODES			18 SUBJECT TERMS (Continue on reverse if necessary and identify by block number)		
FIELD	GROUP	SUB-GROUP			
			impact; acceleration; volunteers; injury tolerance		
19 ABSTRACT (Continue on reverse if necessary and identify by block number)					
<p>Tolerance levels for living human volunteers are defined and developed for minimum risk injury. The experimentally safe levels of impact, derived from a variety of sources, are suggested as guidelines for torso-restrained volunteers, where the freely moving head and neck are the anatomical segments most at risk. These recommended limits are no greater than the maximum exposures already experienced by Naval Biodynamics Laboratory's volunteers. No injuries have been sustained at these levels.</p>					
20 DISTRIBUTION AVAILABILITY OF ABSTRACT <input checked="" type="checkbox"/> UNCLASSIFIED UNLIMITED <input type="checkbox"/> SAME AS RPT <input type="checkbox"/> DTIC USERS			21 ABSTRACT SECURITY CLASSIFICATION Unclassified		
22a NAME OF RESPONSIBLE INDIVIDUAL J. F. Palmer, CDR, MSC, USN			22b TELEPHONE (Include Area Code) 504-257-3922		22c OFFICE SYMBOL 01

GUIDELINES FOR SAFE HUMAN EXPOSURE TO IMPACT ACCELERATION. UPDATE A

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Accession	
NTIS	✓
DTIC	✓
Unannounced	✓
Justified	✓
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PREFACE

"If thou examinest a man having a crushed vertebra in his neck [and] thou findest that one vertebra has fallen into the next one...; his falling head downward has caused that one vertebra [to] crush into the next one; shouldst thou find that he is unconscious of his two arms and two legs because of it... An ailment not to be treated."

Imhotep in Case 33, The Edwin Smith Surgical Papyrus, circa 17th Century B.C.

"At present and for the foreseeable future, quadriplegia can be treated, at best, poorly. It should therefore be prevented when possible."

Kemp Clark, M.D. in Youmans, Neurological Surgery, Vol. 4, 1982.

In the thirty-seven centuries between these two physicians' lives, medical knowledge has burgeoned. This knowledge has helped triple average life expectancy, eradicate killer epidemics and provide artificial organs and prosthetic devices for routine use in humans. Despite this progress, our ability to treat the neurological sequelae of cervical spine injuries is limited by several inherent characteristics of the human nervous system. For example, an injured neuron recuperates poorly, resulting in the permanent severe nerve damage of quadriplegia. Also, the functional specialization of each neuron and the complexity of the interconnections of the brain and spinal cord make substitution or transplanting of different neurons virtually impossible.

The operational Navy must deal with the costs of cervical spine injuries, both with and without neurological damage. Certain naval personnel are prone to cervical spine injuries due to their duties. Aviators, a group with specialized and costly training are especially at risk. A review of Naval Safety Center data from aircraft mishaps using the Information Retrieval System of Aircrew Automated Escape Systems (AAES) developed at the Naval Weapons Engineering Support Activity revealed some of the operational costs of cervical injury [1]. Since 1978, acute cervical spine injuries resulting from aircraft ejections caused eight fatalities, one permanent disability and 44 pilots to lose work for more than one day. These statistics are based only on Flight Surgeon Reports of aircraft mishaps involving ejections, and do not reflect severe neck injuries unrelated to ejections, which can cause significant disability.

The costly effects of most disease can generally be controlled by both prevention and treatment. For cervical spine trauma resulting in death or quadriplegia, prevention continues to be the only treatment. Improving the understanding of the mechanisms of cervical spine injury from biomechanical and physiological perspectives is a crucial aspect of this injury prevention effort.

This is the first update of the initial summary of the best information available relating to human tolerance to impact acceleration [2]. This update

emphasizes -Gx and +Gy acceleration and includes a discussion and review of injury producing exposures as well as recommending safe levels of exposure to impact acceleration.

INTRODUCTION

The Aircrew Impact Injury Prevention program at the Naval Biodynamics Laboratory (NAVBIODYNLAB) includes a group of Navy enlisted men who serve as human research volunteers in a variety of impact experiments. These experiments provide a quality data base for modelling human dynamic and physiological responses to impact and for establishing the relationship between dynamic response parameters and injury. This information will be used by military and commercial designers of emergency and protective equipment to develop and evaluate improved life-protecting systems for short duration (impact) acceleration exposures. Improved protection should significantly decrease the morbidity and mortality associated with escape and recovery systems.

Human volunteer impact acceleration experiments must be conducted at levels of acceleration that may produce discomfort yet have an acceptably low probability of producing any permanent or nonreversible injury. Impact levels that produce human injury and their correlation with dynamic response parameters must be inferred from experiments with human surrogates or from accident epidemiology data. The candidate human surrogates or analogues are human cadavers, animals with morphology similar to humans, and mathematical models. Each of these surrogates may provide valuable and complementary information concerning injury mechanisms and their correlation with human dynamic response data.

Safety requirements for volunteer experiments result in recommended acceleration exposure limits that are below acceptable operational levels. This is an important distinction. Safe experimental limits can be considered a level below which there is negligible risk of any serious injury. Survivable limits which may permit severe injury provide an upper level for acceptable operational exposure. The objective of the review and analysis included in this report and future updates is to narrow the gap between these upper and lower limits to the maximum extent possible. This information will prove valuable to those concerned with ensuring that Navy and Marine Corps personnel can safely and effectively accomplish their mission.

HUMAN ACCELERATION

EVALUATION OF NAVBIODYNLAB EXPERIMENTAL SEVERITY AND RISK

The single most important consideration in impact experiments is to conduct them in a manner which minimizes the risk of any permanent or nonreversible injury to the subject, while providing valid information required to meet program objectives. To obtain valid and meaningful data, some acceptable risk of injury to the human subject must be defined. The goal at the NAVBIODYNLAB is not to expose human volunteers to impact levels that have a high risk of producing injuries or that compromise the future health and well-being of the

subjects. This policy contrasts with operational conditions, where tolerance levels for crash survival may permit injury levels which are not acceptable for human experiments conducted in a laboratory. Examples of unacceptable injuries are: any bone fractures; vertebral dislocations; disc herniations or fracture of disc endplates; ligament avulsion; serious disruption of blood vessels; damage to internal viscera or supporting ligaments that result in any chronic impairment of health or loss of function. However, experiments may produce minor injuries such as muscle soreness, acute tissue strains, external fascia abrasions and contusions due to restraint interfaces with the subject. Other examples of acceptable injuries are: short-duration mild headaches; brief periods of bradycardia (i.e., a few complexes) or tachycardia occurring immediately after the impact exposure which progressively return to normal rates; other anomalies or arrhythmias in the EKG complex not considered medically significant which return to normal in a brief period. Brief "stunning" or mild concussion similar to that observed in sports activities, which is free of residual medical effects, is also acceptable in impact research.

The severity of an abrupt acceleration exposure is a complicated function of the duration and magnitude of the acceleration pulse, the direction of the acceleration vector relative to the anatomical axes, and the restraint of the human subject. For simple, unimodal acceleration profiles, severity is a function of one or more of the following variables:

- (1) Direction of acceleration relative to the subject's anatomy;
- (2) Peak level of the acceleration pulse;
- (3) Rate of onset of the acceleration pulse (how rapidly the acceleration rises to its peak level);
- (4) Duration of the acceleration pulse (the length of time the acceleration remains above a fixed fraction of its peak level);
- (5) Rate of offset of the acceleration pulse (how rapidly the acceleration falls from its peak level);
- (6) The subject's posture and restraint;
- (7) The static and dynamic tension of the restraint prior to impact.

The interactions of these variables are complex. Variables (1) - (5) define severity levels only when the human subject is restrained in a consistent and repeatable fashion.

EXPOSURES EMPLOYED IN PREVIOUS RESEARCH WITH HUMAN SUBJECTS

Experimental data and medical effects from past experiments at the NAVBIODYNLAB provide a basis for recommending other experiments which do not exceed these previous impact levels. Tables 1-3 present summaries of the results from the most severe tests conducted at NAVBIODYNLAB.

Table 1 lists the parameters describing the sled acceleration profiles for these tests. The number of subjects, initial conditions, and restraints are also defined in this table.

Table 1: Most Severe NAVBIODYNLAB Test Conditions

-----SLED ACCELERATION----- ENDSTROKE					NO.OF SUBJ.	REMARKS
DIRECTION	PEAK (g)	ONSET (g/s)	DURATION (ms)	VELOCITY (m/s)		
-X	15.9	1522	99	18.0	13	EBO = Eyeballs out
-X	15.6	484	93	18.0	17	EBO
-X	15.5	2129	25	4.2	11	EBO
+Y	7.2	693	78	6.3	20	EFR = Eyeballs right
+Y	7.2	162	66	6.5	29	EBR
+Y	11.3	1433	28	3.5	20	EBR
-X+Y	7.1	784	105	8.9	13	EBOR = Eyeballs out & right
-X+Y	9.1	899	87	9.0	5	EBOR
-X+Y	11.4	342	101	14.8	3	EBOR
-X+Y	9.2	235	74	9.0	19	EBOR
-X+Y	13.0	1987	27	3.8	16	EBOR

RESTRAINT:

-X: Seated upright, shoulder and lap belts, inverted v pelvic strap attached to lap belt.

+Y, -X+Y: Additional padded sideboard against right shoulder.

Table 2 contains torques and forces at the head-neck joint (occipital condyles¹) for tests involving the most severe g levels used at NAVBIODYNLAB. These parameters which relate to injury tolerance are derived from measurements made on the head and neck during these tests.

Table 2: Estimated Forces and Torques at Condyles (Head-Neck Joint)

-----SLED ACCELERATION----- ENDSTROKE					MAXIMUM FORCES*				MAXIMUM TORQUES**			
DIRECT'N	PEAK (g)	ONSET (g/s)	DURATION (ms)	VELOCITY (m/s)	Fx (N)	Fy (N)	Fz (N)	FR (N)	Tx (Nm)	Ty (Nm)	Tz (Nm)	TR (Nm)
-X	15.6	539	89	17.6	-1000	<100	-750	1200	-60			60
+Y	7.1	167	75	6.9	-260	400	-305	490	-33	-15	11	35
+Y	11.2	1349	28	3.5	-194	294	-322	415	-21	-6	8	22
-X+Y	11.4	337	101	14.9	-675	363	-620	900	-31	-45	12	50
-X+Y	13.1	1972	26	3.8	-341	255	-205	448	-25	-27	16	36

*Peak forces for each direction and peak resultant force are given in Newtons. One Newton is equivalent to .22 lb.

**Peak torques for each direction and peak resultant torque are given in Newton-meters. One Newton-meter is equivalent to .74 ft-lb.

¹The occipital condyles are at the base of the skull and rest on the superior facets of the first cervical vertebra (C1).

Table 3 shows the peak angular acceleration, angular velocity, and linear acceleration for representative NAVBIODYNLAB maximum severity exposures [3] in the -X and +Y directions. These data are used to define tolerance levels based on shear failures.

Table 3: Average Peak Resultant Head Kinematic Values

DIRECTION	ANGULAR ACCEL. (rad/s ²)			ANGULAR VELOCITY (rad/s)			LINEAR ACCEL. (m/s ²)			PEAK SLED ACCEL. (g)
	HOLD	HOSD	LOLD	HOLD	HOSD	LOLD	HOLD	HOSD	LOLD	
-X	1800	1600	1600	35	27	35	285	200	245	15
+Y	1030	860	900	26	20	24	130	78	123	7
+Y		1600			32			115		11
-X+Y			1107			28			200	11
-X+Y		1384			28			174		13

HOLD: High onset (2000-20000 g/s), long duration (60-120 ms)
HOSD: High onset, short duration (20-35 ms)
LOLD: Low onset (< 2000 g/s), long duration

MEDICAL FINDINGS

The summarized medical findings in the NAVBIODYNLAB impact exposure data include:

(1) Headache was the most common finding immediately after impact, and reflects exposure severity in both the -X and +Y directions. The headaches were occasionally severe for up to one minute, but always diminished with no sequelae.

(2) Muscular myalgia was common on the side of the neck opposite head motion for exposure in the +Y direction. These neck problems have not been observed in the -X direction. One subject, tested in the -X+Y direction had a sore neck that persisted for two weeks before recovery. Subsequent medical examinations, as part of the NAVBIODYNLAB long-term follow-up program², revealed no sequelae in this subject.

(3) Cardiac findings for the -X and +Y directions were mostly medically insignificant [4].

(4) One subject had pain radiating to his left arm after a +Y exposure. This condition was diagnosed as a stretched brachial plexus. He recovered with no sequelae.

² Eighty percent of the subjects with the highest cumulative exposures are brought back after a period of three to five years and given the same medical examination that was given at their entrance and discharge from the program.

Some additional +Y impact data from experiments conducted at other laboratories are available [5]. In most of these experiments, the head and neck were restrained and the subjects were exposed to high g-levels (20-30 g) without injury. In one series of NAVBIODYNLAB experiments [6], human subjects were exposed to +Y impact levels of 12 g with upper torso restraint and to 9 g without upper torso restraint. Head and neck restraints were not used for either of these exposures. Although no permanent physiological effects were noted in these experiments, physical complaints (such as neck stiffness) occurred after most tests above 6 g. Therefore, with the head and neck unrestrained, head angular deflection should be considered the limiting safety factor.

The "Eiband curves" [7] for human wholebody tolerance to impact acceleration exposures are based on work with humans and chimpanzees carried out in the late 1950's. These frequently referenced [e.g., 8] curves summarize estimated Gx tolerance levels with the torso under restraint conditions similar to the experiments conducted at the NAVBIODYNLAB suggesting that these exposures are tolerated by the head and neck as well. These estimates can be summarized as follows for the -X direction:

35-40 g (onset <1000 g/s)
30 g (onset >1000 g/s), duration < 100ms
20-25 g, duration > 200 ms

Moderate head-neck related dysfunction (occasional stunning) has been reported as low as 12 g with onset and duration 226 g/s and 106 ms respectively [9]. More severe stunning and disorientation lasting 10 to 15 seconds post-impact were reported at 20 g ([10] as cited in [9]).

It is important to note that these data were obtained using decelerative devices which may have provided significant dynamic preload protection [11] when compared to the non-preload impact delivered in the NAVBIODYNLAB experiments.

INJURY CRITERIA

Linear acceleration

Many injury criteria have been developed relating the acceleration profile of the head to survivable head injury. One excellent discussion describing the supporting models and definitions of many of these head injury-related criteria is available [12]. Most linear acceleration criteria were originally derived from the Wayne State Tolerance Curve (WSTC) [12]. The WSTC uses skull fracture as the criterion for injury and has little value in assessing the effect of indirect impact to the head as experienced in the experiments at NAVBIODYNLAB. Another commonly used criterion, the Gadd Severity Index (GSI) has been extended to assess the effects of indirect impact. Discussions of the origin and important limitations of this particular index are available [12, 13, 14].

The linear relationship between intracranial pressure and peak acceleration [15] suggests that acceleration and duration may be better indicators of injury than the GSI which is computed using acceleration raised to a power.

Angular acceleration and velocity

Angular acceleration and velocity have been incorporated in a model of head injury based on shear stress [13]. The tolerance criteria developed from this model used data from rhesus and squirrel monkey experiments. These data were scaled to humans using brain mass ratios and a shear failure model. Limiting values were determined for angular acceleration and velocity which predicted a 50% probability of concussion (without direct impact to the head) in humans having a brain mass of 1.3 kg. Though the scaling of the model to humans is not validated, these values were suggested as possible tolerance levels.

Index	Injury Level	References
Angular acceleration	< 1700 - 1800 rad/s ²	[13, 16]
Angular velocity	< 20 - 30 rad/s	[13, 16]

From Table 3, the NAVBIODYNLAB average maximum peak angular acceleration during the 41 -15 Gx tests was 1800 rad/s², which produced no detectable concussion. This indicates that the suggested limits on angular acceleration and velocity are far too conservative. This is also supported by Col. John Stapp's test exposure on the rocket sled at -45.4 Gx [17] which produced no central nervous system injury. For indirect impact in the +Y direction, NAVBIODYNLAB data on the unrestrained head and neck indicate that neck-related problems such as severe strains precede head injury, and therefore neck injury is the limiting factor in defining maximum impact exposures.

Forces and torques

The human head has a mass of approximately 4.5 kg with an internal brain mass of approximately 1.3 kg. The base of the skull (the occipital condyles) rests on the superior facets of the atlas (C1). Head loads are transmitted through the cervical spine, thoracic spine, and lumbar spine to the pelvis. With a fully restrained torso, the head loading of the cervical spine produces injury by producing neck forces and moments which exceed the neck's injury tolerance limits.

Injury thresholds for the neck [13, 18, 19, 20, 21] are expressed in terms of the equivalent torque at the occipital condyles and the shear and axial forces at the condyles. The equivalent torque at the condyles is the torque that the neck produces on the head that is consistent with the mass distribution properties of the head (mass, moment of inertia, center of gravity), the location of the head-neck joint (condyles), and the observed kinematic motion of the head. The equivalent torque is sensitive to the location of the head center of gravity relative to the condyles. This is a significant factor in limiting the precision of computing torque thresholds. The force components are robust and not sensitive to geometric configuration factors. Suggested injury threshold levels use data from static tests on living human volunteers, and dynamic tests on human volunteers and human cadavers. Published data [18, 21, 22] indicate that injury thresholds based on cadaver experiments are approximately 50% to 100% greater than thresholds based on the limits of voluntary human tolerance.

All cervical joints, from the atlanto-occipital joint to C7-T1, have some degree of flexion-extension and lateral bending [23, 24, 25]. All joints except the atlanto-occipital joint also have some capacity for axial rotation. The normative limits of these ranges of motion should not be exceeded. Extensions should be kept within 60 degrees [24]. Lateral flexion should be kept within 52 degrees [20]. Axial rotations should be kept within ± 47 degrees for C1-C2 (atlas-axis) and ± 94 degrees for C1-C7 [23].

Based on work with human volunteers and the Hybrid III dummy, the tension, compression and shear loads for injury of the cervical spine have been determined [20] and are shown in Figure 1. Additionally, injurious torques are identified [21] as:

C1 (condyles):

flexion 190 Newton-meters (Nm)
extension 57 Nm
lateral >57 Nm, <190 Nm

C7/T1:

flexion 380 Nm
extension 114 Nm
lateral >114 Nm, <380 Nm

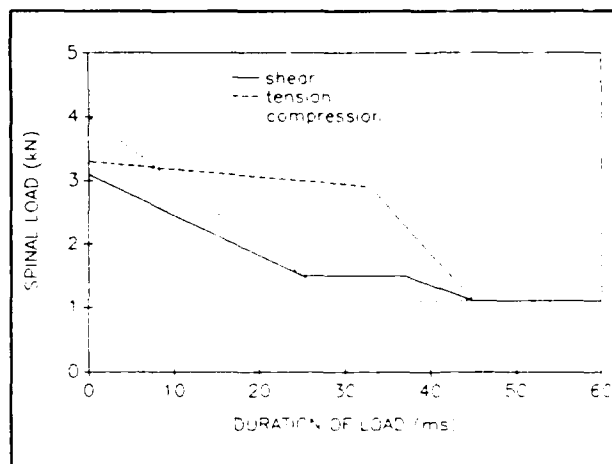


Figure 1: Suggested spinal force-time limits for injury assessment [20].

Axial tension forces are generated at the spinal ligaments during neck movements. The static force to failure of cadaveric cervical ligaments [26] has been measured in detail. These ligaments are necessary for stabilizing the cervical vertebrae and for protecting the spinal cord [27] and in dynamic tests to failure, anterior ligaments routinely fail before posterior ligaments [28]. Adequate models for transferring this information to useful estimates of injury thresholds are lacking.

SUMMARY

The tolerance levels for living human volunteers are defined and developed only for minimum risk injury. Human volunteers are not intentionally exposed to impact levels that have a high risk of producing injuries or that compromise the future health and well-being of the subjects. This policy contrasts with operational conditions, where tolerance levels for crash survival may permit injury levels which are not acceptable for human experiments conducted in a laboratory. Consequently, safety requirements for volunteer experiments may result in recommended exposure limits that are below survivable acceleration levels. This is an important distinction. Safe experimental limits can be considered a level below which there is negligible risk of any serious injury. Survivable limits which may permit severe injury provide an upper level for operationally permissible exposure.

The experimentally safe levels of impact, derived from a variety of sources, are suggested as guidelines for torso-restrained volunteers, where the freely moving head and neck are the anatomical segments most at risk. These safe guidelines for the -X, +Y and -X+Y directions are:

DIRECTION	SLED ACCELERATION		SLED END STROKE VELOCITY (m/s)
	PEAK (g)	DURATION (ms)	
-X	16	100	18
+Y	7	<80	<7
+Y	12	<30	<4
-X+Y	11	100	15
-X+Y	13	<30	<4

These recommended limits are no greater than the maximum exposures already experienced by NAVBIODYNLAB subjects. No injuries have been sustained at these levels. The limits in the +Y and the -X+Y direction are due to potential severe neck strain. This condition was related to the maximum head angle relative to the neck angle, and can be controlled by limiting the endstroke velocity as the g-level is increased. This is reflected in the two sets of limits for these directions.

Based on review of non-NAVBIODYNLAB data some additional information regarding -X exposure is available. Occasional mild stunning occurs at 12g [9], severe stunning at 20g ([10], as cited in [9]), and vertebral fractures and shock at 34g [11]. These data suggest that an operational limit in the -X direction might be 20g for effective post-impact mission survivability.

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